HIPAA, FERPA, IRBs – Do They Impact AHEC Data Collection Methodologies?

Panel participants Sarah Crabtree, Compliance Project Manager, Indiana University; Stephanie Fofonoff, Administrator, Institutional Review Board of Billings, MT; and Shelly Witter, Compliance Program Director & Privacy Officer, UTMB.

US. Department of Health and Human Services (HHS)

Health Resources and Services Administration (HRSA)

Bureau of Health Professions (BHPr)

Division of Public Health and Interdisciplinary Education (DPHIE)

Area Health Education Center (AHEC) Branch

AHEC Training and Consultation Center (A-TrACC)

HIPAA and FERPA 101

Shelly Witter
University of Texas Medical Branch
Director of Compliance Programs & Privacy Officer

What is Privacy?

- Ensuring individuals have control over their own personal information
- Personal information today is more than your name, address, social security number (SSN)
  - Medical information
  - Work history
  - Credit score
  - Shopping habits

Confidentiality

- How an entity treats or handles the personal information of an individual
- Expectation from the individual that their personal information isn’t used or disclosed in a way that impermissible/inappropriate

Health Insurance Portability and Accountability Act of 1996 (HIPAA)
The Basics

- Federal law
- Standards for transactions and code sets
- Privacy Rule - protects the privacy of individually identifiable health information and gives patients rights over their health information
- Security Rule - sets national standards for the security of electronic protected health information

HIPAA – *Protected Health Information (PHI)*

- "Individually identifiable health information", including demographic data, that relates to:
  - Individual's past, present or future physical or mental health or condition,
  - Provision of health care to the individual, or
  - Past, present, or future payment for the provision of health care to the individual
- Maintained or transmitted by a covered entity or its business associate
- Can be electronic, paper, or oral

HIPAA – *Does it apply to AHECs?*

- To a limited degree
- “Covered entity” is a health care provider who transmits health information in electronic form in connection with transactions for which the Secretary of HHS has adopted standards under HIPAA
- Very unlikely that the data maintained by AHECs fit this criteria

Family Education Rights and Privacy Act of 1974 (FERPA)
The Basics

- Federal law
- Protects the privacy of student education records
- Students have specific, protected rights regarding the release of such records
- Requires that institutions adhere strictly to these guidelines

FERPA – *Education Records*

- Information directly related to a student's career that are maintained by an educational agency or institution
- Excludes:
  - Records created for staff's own use and not disclosed
  - Records of the campus police
  - Records created, maintained, and used in connection with student's medical treatment or counseling exclusive to the provider
  - Records created or received post-attendance not directly related to the person's attendance as a student
  - Grades on peer-graded papers before they are collected and recorded by an instructor
  - Employment records unrelated to the student's status as a student
  - Alumni records

FERPA – *Student Rights*

- Inspect and review their educational records
- Consent to the disclosure of their education records (exceptions exist)
- Request amendment of educational records
- File complaint for disclosures that violate FERPA

FERPA – *Consent Exceptions*

- Directory information
- School officials with legitimate educational interests
- Officials of educational institutions in which that student seeks or intends to enroll or is enrolled
- Audit or evaluation of federal or state education programs
- Organizations conducting studies
- Accrediting organizations
- Financial aid
- State and local officials pursuant to statute concerning juvenile justice
- Parents of dependents
- Judicial order or subpoena
- Health and safety

FERPA and Research

- FERPA and human subject protection regulations apply when accessing educational records for research purposes so make sure you involve your IRB
- Research is not always considered a legitimate educational interest
- Options to obtain data
  - Obtain written consent for each individual whose education records will be accessed for research purposes
  - Researcher provided data that has been stripped of any identifying information by school official with legitimate interest (not the researcher)
  - Exception to consent exists

FERPA – *Use of "De-Identified" Data*

- Removal of all personally identifiable information
  - Direct personal identifiers (student name, SSN, student #)
  - Indirect identifiers (name of the student's parent or other family members; addresses; date and place of birth; mother's maiden name; etc.)
  - Biometric records, including one or more measurable biological or behavioral characteristics that can be used for automated recognition of an individual (fingerprints; voiceprints; facial characteristics; handwriting)
  - Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty

FERPA – *Disclosures to Organizations Conducting Studies*

- Studies, on behalf of the institution related to:
  - Development, validation, or administering predictive tests;
  - Administering student aid programs; or
  - Improving instruction
- Required written agreement that:
  - Specifies the purpose, scope, duration of the study and the information to be disclosed
  - States the information from the education records will only be used to meet the purpose of the study as stated in the agreement
  - Specifies the study will be conducted in a manner that does not permit personal identification of parents and students by anyone other than representatives of the organization with legitimate interests
  - Specifies that all personally identifiable information will be destroyed or returned to the institution when the information is no longer needed for the purposes of the study and specifies the time period in which the information must be destroyed or returned

Questions?????

IRBs 101

Sarah Crabtree, MS, CIP
Compliance Project Manager
Clinical Research Compliance Office
Indiana University

Learning Objectives

- Appreciate the history of human subject protection in research
- Understand why IRB review is necessary
- Know the role of the IRB
- Realize potential consequences if appropriate IRB approval is not obtained
- Identify when IRB review is applicable
- Become familiar with the different levels of IRB review

Why IRB Review?

- History
  - 1948: Nuremburg
  - 1950: Thalidomide
  - 1964: Helsinki
  - 1932-1971: Tuskegee Syphilis Study
  - 1974: National Research Act
  - 1979: The Belmont Report
  - 1981: DHHS and FDA issued regulations based on the Belmont Report
  - 1991: The Common Rule

Tuskegee Syphilis Study –1932-1971

- Who:
  - Researchers who were monitored and funded for 40 years by the U.S. Public Health Service
- What:
  - Conducted longitudinal study of the effects of untreated syphilis in low-income, African-American males
  - Participants received lumbar punctures to monitor disease progression under the guise that they were a type of medical treatment
- Where:
  - Tuskegee, Alabama

Tuskegee Syphilis Study –1932-1971

- Ethical Issues:
  - Coercion/payment
    - Participants were promised funeral benefits for participating
  - Risks to subjects & Deceit
    - Study did not minimize risks to human subjects. In fact, it increased their risks.
    - Participants were told they were not allowed to seek treatment elsewhere, even after it was discovered that penicillin would cure the disease in 1943, the treatment was not given and
  - Vulnerable population
    - Used disadvantaged, rural black men to study the untreated course of a disease not confined to that population.

Belmont Report - 1979

- Who: The National Commission
- What:
  - Issued the Belmont Report, a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects.
  - Cornerstone of today's regulations involving human subjects
  - Direct Impact on Human Subjects Research:
    - Three basic ethical principles
      - Respect: informed consent, acknowledge autonomy
      - Beneficence: protection from harm, risk/benefit analysis
      - Justice: equitable selection of subjects

The Belmont Report: An Ethical Framework

- Three basic ethical principles
  - Respect: informed consent
  - Beneficence: protection from harm, risk/benefit analysis
  - Justice: equitable selection of subjects
- Cornerstone of today's regulations involving human subjects

Current Regulations

- 1981: DHHS and FDA issued regulations based on the Belmont Report
  - 45 CFR 46 (DHHS)
  - 21 CFR 50 (FDA – protection of human subjects)
  - 21 CFR 56 (FDA – Institutional Review Boards)
- 1991: The Common Rule
  - 45 CFR 46, Subpart A: Adopted by 17 other Departments and Agencies
  - Most (but not all) of the federal Departments and Agencies conducting human subjects research

The Common Rule

- Applies to all human research regulated by the federal government
- IRBs must review subject selection procedures, informed consent, and the research plan itself
- Establishes criteria for exemption and expedited review
- Informed consent
  - Required elements
  - Documentation
- Subparts B, C, and D: Additional protections for vulnerable populations
  - Pregnant Women
  - Children
  - Prisoners

Assuring Compliance

- Federal-wide Assurances
  - The DHHS Office for Human Research Protections (OHRP) requires a policy statement "Assurance“, that sets forth the procedures used to protect human subjects and assures compliance with the Common Rule
  - Filed by all institutions conducting human subjects research supported by DHHS
  - Approved by the Office for Human Research Protections (OHRP)
  - Failure to comply can result in revocation of the FWA

Institutional Review Board

- Independent panel that reviews proposed research to protect the rights and welfare of human participants
- At least five (5) members (both genders)
- Diversity and appropriate expertise
- Varied professions (scientists and non-scientists)
- At least one unaffiliated member
- Knowledge/sensitivity of community attitudes
- Knowledge of vulnerable populations
- Ad hoc consultants

Role & Authority of IRB: Protect Human Subjects

- Approve or disapprove research and require modifications
- Conduct initial and continuing review at least annually
- Must approve any changes in research before they can be implemented
- Evaluate unanticipated problems and noncompliance
- Suspend or terminate approval of research

The IRB Review Process

- **Requirements for Approval**
  - IRB must assure:
    - Risks to subjects are minimized
    - Risks to subjects are reasonable in relation to anticipated benefits
    - Selection of subjects is equitable
    - Monitoring of data is adequate to ensure the safety of subjects
    - Additional safeguards are in place to protect subjects vulnerable to coercion
- All these must be determined at initial review

Terms to Know

- **Research:** A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge
  - Systematic Investigation typically involves a predetermined method for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory.
  - Develop or contribute to generalizable knowledge typically requires that results (or conclusions) of the activity are intended to be extended beyond a single individual or an internal program.

Terms to Know

- **Human Subject:** A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.
  - Intervention includes both physical procedures (e.g. venipuncture) and manipulations of the living individuals or the living individuals' environments.
  - Interaction includes communication or interpersonal contact between the investigator (or research team) and the living individual.

Terms to Know

- **Human Subject** (Cont'd):
  - Information is considered identifiable if (1) the identity of the individual from whom the information was obtained is ascertained or may be readily ascertained by the investigator; or (2) the identity of the individual from whom the information was obtained is associated or may be readily associated with the information.
  - Private information includes information about behavior that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place or information that has been provided for specific purposes that the individual can reasonably expect will not be made public (e.g. medical records, employee or student records).

Terms to Know

- **Minimal Risk.** The risks of harm anticipated in the proposed research are not greater considering the probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological exams or tests.

Do I need IRB review?

- Questions to Ask:
  - Is my activity a systematic investigation and designed to develop or contribute to generalizable knowledge?
    - If "yes" to both, your activity involves research.
    - If "no" to one or both, your activity does not involve research
  - Does my activity involve obtaining data about a living individual through intervention or interaction with the individual or identifiable private information?
    - If "yes" to one or the other, your activity involves human subjects.
    - If "no" to both, your activity does not involve human subjects.

Types of IRB Review

- Research Not Subject to the FDA or Common Rule Definitions of Human Subjects Research**
  - Research, but NOT human subjects (deceased individuals, limited data set, de-identified data)
- Exempt Review
  - Research specifically exempted from IRB review
- Expedited Review
- Full Board Review

- **Individual institutions have different requirements for submission and oversight of Exempt research and research not meeting the definition of Human Subjects Research. Check with your institution for specific types of submission and review requirements.

Research Vs. Quality Improvement

Research	Quality Improvement
Research projects must meet IRB requirements for protection of human subjects.	Quality Improvement projects are not covered by IRB requirements.
Characteristics of Research: • One of the main goals is to advance general knowledge in the academic, scientific, or professional community. • Specific hypothesis or research question. • Involves an organized review of relevant literature. • Conducted using a research design that will lead to scientifically valid findings. Elements of a research design include: control groups; random selection of subjects, statistical tests, sample design, etc. • Most of the patient/subjects are not expected to derive a personal benefit from the knowledge gained. • One goal of the project is to generate, evaluate or confirm an explanatory theory or conclusion and invite critical appraisal of that conclusion by peers through presentation and debate in public forums.	**Characteristics of Quality Improvement:** • Identifies specific services, protocols, clinical practices, or clinical processes or outcomes within a department, clinical program or facility for improvement. • The project team may review available literature and comparative data, or clinical programs, practices or protocols at other institutions in order to design improvement plan, but do not plan a full scientific literature review. • The project design uses established quality improvement methods (such as PDSA cycle) aimed at producing change within a program. • The project design does not include sufficient research design elements to support a scientifically valid finding. • Most of the patients who participate in the project are expected to benefit from the knowledge gained. • The project does not impose any risk or burden on the patients.

Exempt

- Research activities that present no more than minimal risk; and
- Research involving only procedures listed in the federal regulations
- Reviewed by an IRB staff member
- Examples:
  - observation of public behavior
  - collection or analysis of existing data
  - surveys

Expedited Review

- Must fall under one of 7 expedited categories
- Examples:
  - Surveys, interviews
  - Prospective collection of data
  - Research on individual or group characteristics
  - Research employing oral history, focus groups, or program evaluation

Full-Board Review

- Greater than minimal risk
- Reviewed by the full IRB committee
- Examples:
  - Experimental drug or device studies
  - Most invasive procedures
  - Surveys/interviews that include sensitive questions or questions that are likely to be stressful to the subject
  - Many types of research involving children, pregnant women and fetuses, cognitively impaired, and research involving prisoners

What can happen if research is not reviewed and approved by the IRB?

- The data collected may not be used for research purposes, i.e. the research can not be published or presented (more journals are checking)
- The IRBs can impose or have imposed sanctions on investigators that conduct research without prospective IRB approval
- IRBs must notify the federal government of any serious or continuing noncompliance

ANPRM

- Advanced Notice of Proposed Rulemaking (ANPRM) for Revisions to the Common Rule
  - Changes that could impact Exempt research
    - Change from “Exempt” to “Excused”
    - Expansion of Exempt categories
    - Requested feedback regarding researchers “registering” their studies instead of institutional review
  - **Goal:** Increase protections and broaden the types of studies that would qualify for exempt category

Points to Remember

- Use your resources
  - DHHS, OHRP, FDA website
  - Your institutional or local IRB office
  - Departmental contacts, mentors

  - Call/email your resources early and often

Thank You!

For questions and information, please contact:
Sarah Crabtree
(317) 274-6932
scrabtre@iupui.edu

Helpful Website Resources:

http://www.hhs.gov/ohrp/humansubjects/index.html

http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm155713.htm

http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html

Institutional Review Board (IRB) of Billings

Billings, Montana

Stephanie Fofonoff BS MHA
Administrator

Certified IRB Professional

Affiliations: Billings Clinic

& St. Vincent Healthcare

IRB of Billings

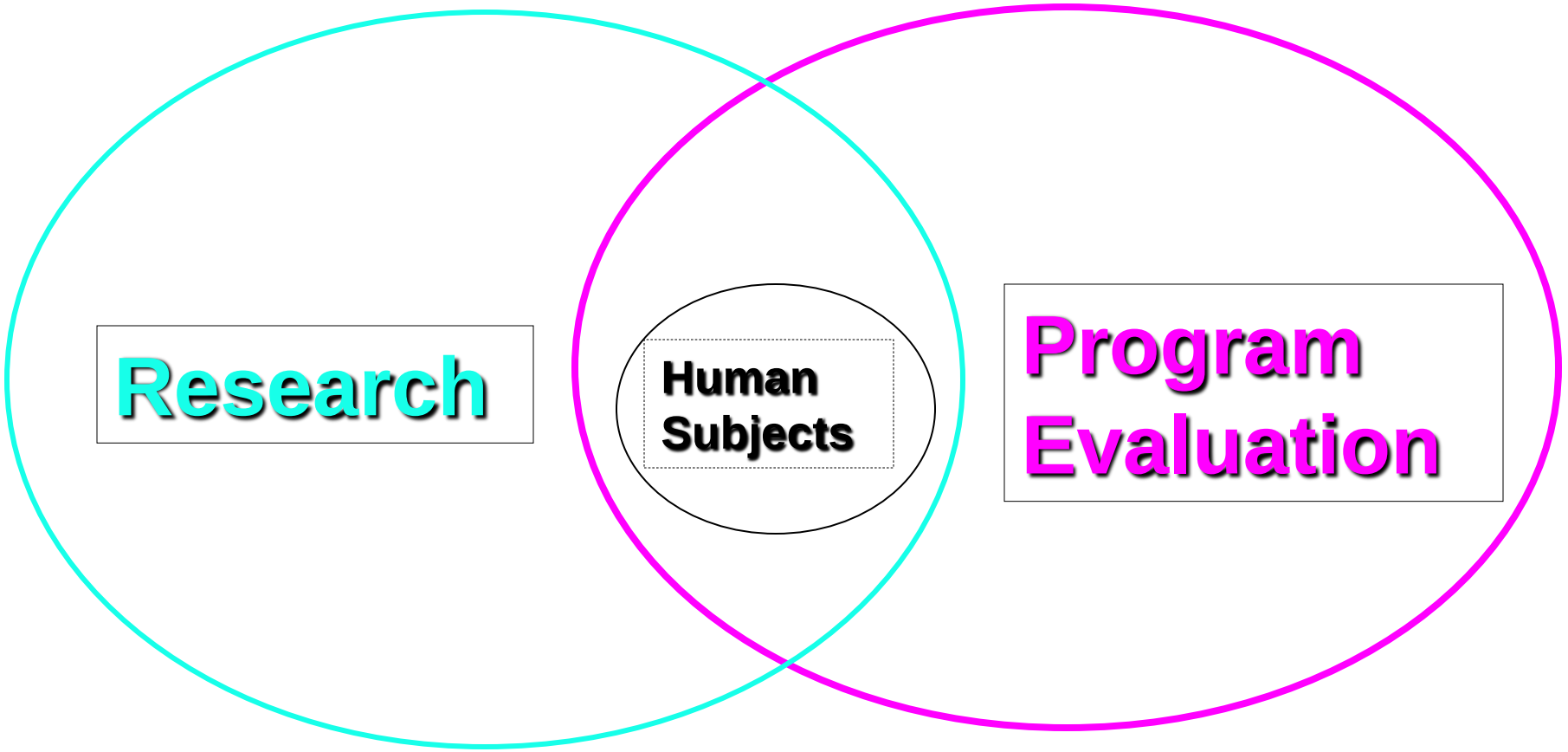
. . . Jurisdiction . . .

- Research conducted or originating in Billings region
- Local research organizations
- Participating rural sites and neighboring states
- National cancer trials in Montana

Distinguishing *Program Evaluation* from *Human Subjects Research*

Program Evaluation Research involving Human Subjects

IRB approval required



Research – Scientific & “systematic” design

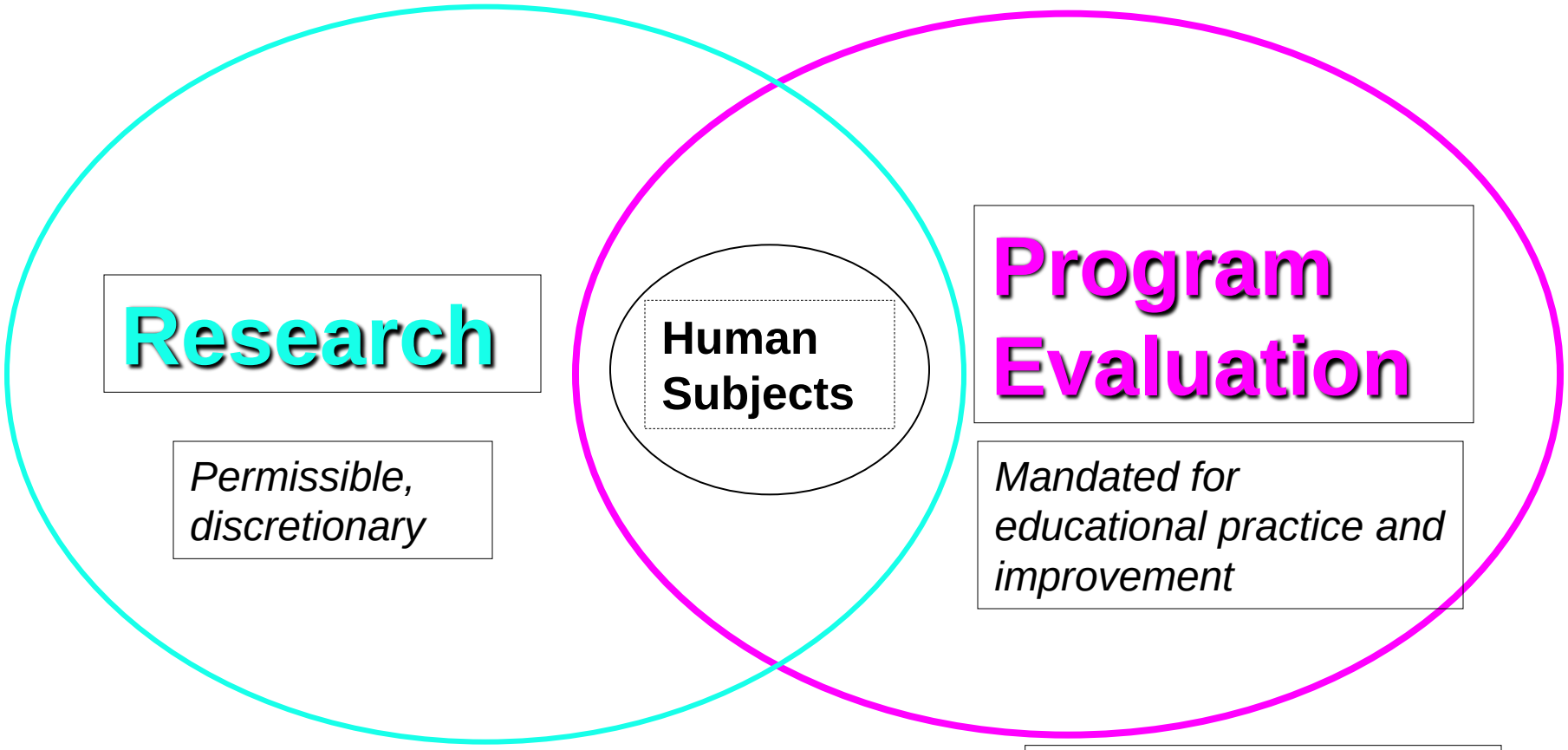
- Linear & forward
- Uniform steps
- Experimental method
- Controlled variables
- Generates new knowledge
- For future use in future population

Program Evaluation – Learning from experience

- Part of design & development
- Collects & provides feedback
- Participatory & collaborative
- Provides learning & tools
- Real-time applications to improve an educational program or service

Program Evaluation Research involving Human Subjects

IRB approval required



Defining Research . . .
the “grey zones”

- Program Evaluation
  - **May include a research component**
- Quality improvement (QI) or assurance (QA)
  - **May be research when intent is generalizable knowledge**

Distinguishing Program Evaluation from Research: *Why?*

To spare the time, effort and resources
of formal application to an IRB

Catch – 22

To rule out research,
the IRB may require detailed information
about the proposed activity or program

Distinguishing Program Evaluation from Research: *How?*

- Examine each activity, case-by-case
- Apply the principles, and
- Consult the regulations

Area Health Education Centers (AHEC)

Example of a Program Definition:

AHEC Health Careers Enrichment Activities

"A curriculum or set of educational enrichment and academic support activities of a specified length"

Purpose: To improve an educational program or service

Area Health Education Centers (AHEC)

SPECIAL CONSIDERATIONS
For Research

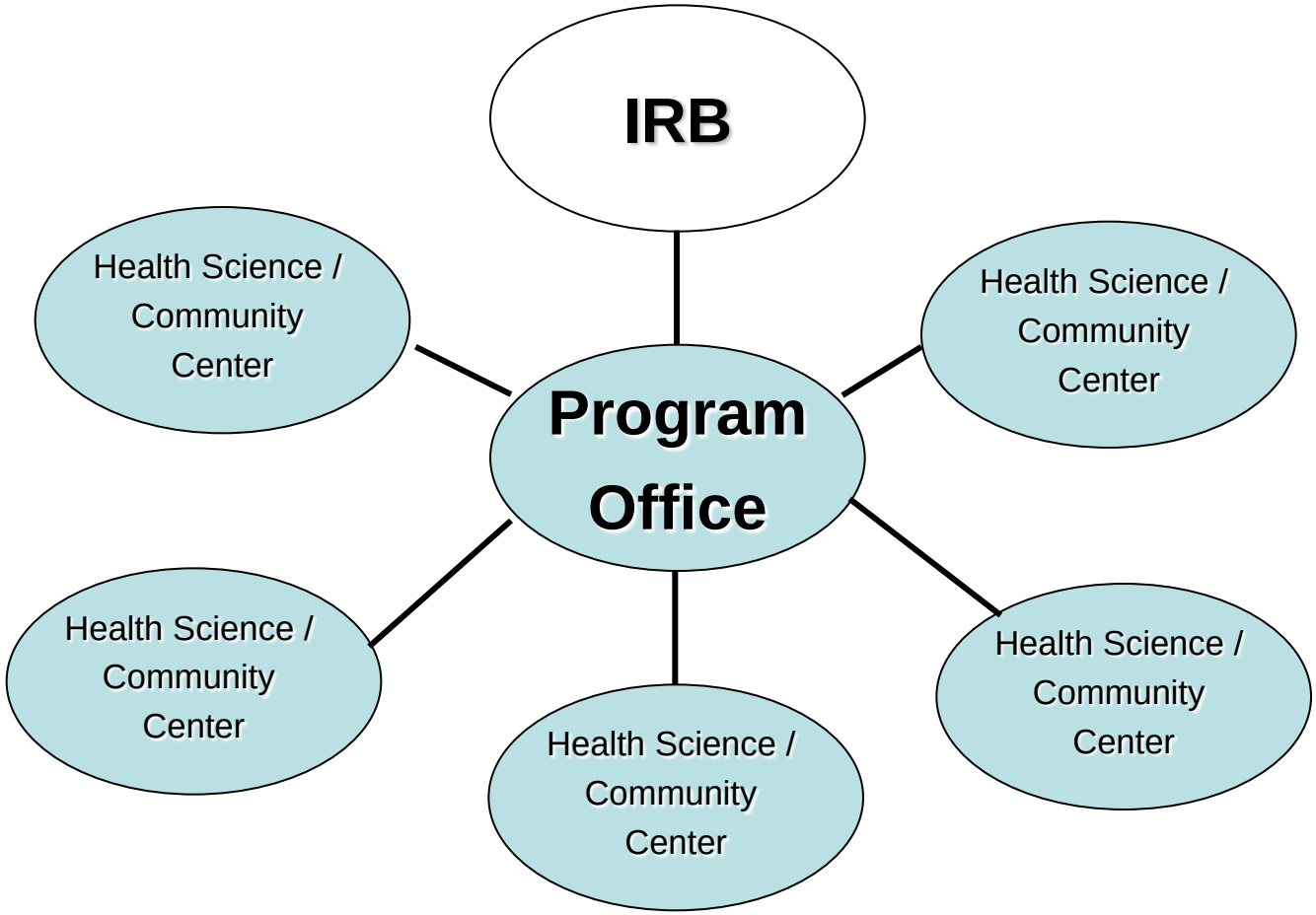
Family Educational Rights & Privacy Act (FERPA)
The Protection of Pupil Rights Amendment (PPRA)

Includes MINORS – Grades K-6, 7-8, 9-12

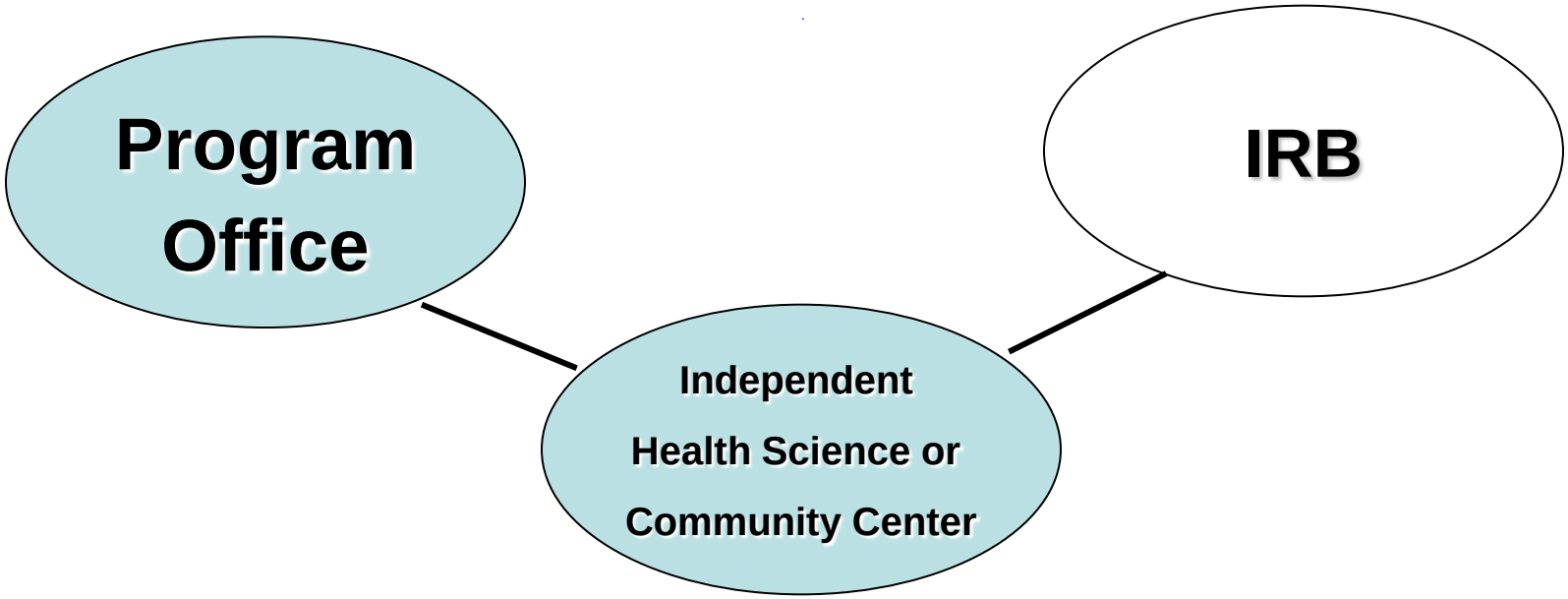
Distinguishing Program Evaluation from Research: *Who Decides?*

- Not the function of the IRB to distinguish between research and nonresearch
- Nor should the investigator make this determination
- Therefore, the institution should develop a process. *(See Recommendations)*

Research vs. Program Evaluation: *Who decides?*



Research vs. Program Evaluation: *Who decides?*



Recommendations

Don’t say that Program Evaluation is research involving human subjects, if it isn’t.

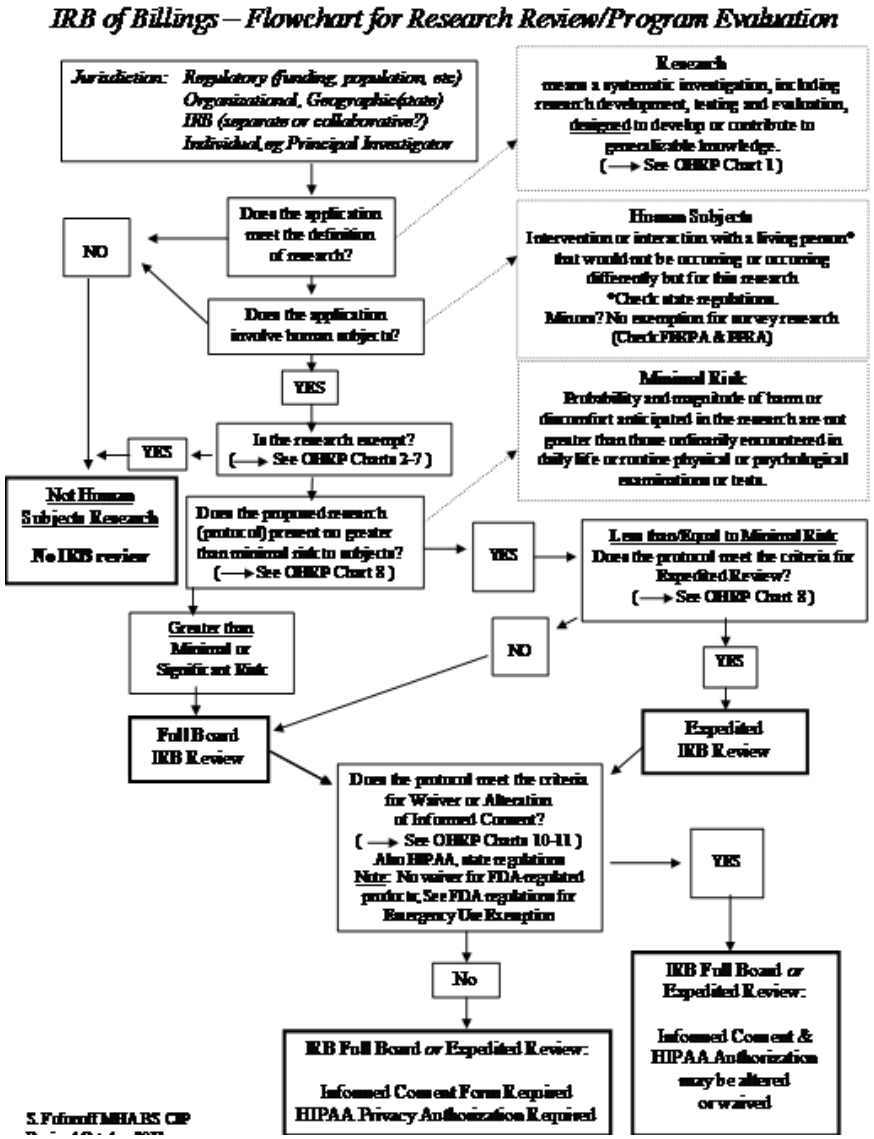
Establish institutional policies and procedures to

- Review each Program Evaluation project and determine when the Program Evaluation involves research
- Determine when research is exempt
- Determine when research needs IRB review for approval

If the activity IS determined to be *research* . . .

IRB Flowchart for Research Review

Complexity



IRB Flowchart for Research Review

Jurisdiction

- Geographic
- Regulatory
- Organizational
- Individual

Jurisdiction for Community IRB - Geographic, Regulatory, Organizational, Individual

ORG. JURISDICTION
(Local PI Affiliation)

LOCAL (regional)

LOCAL HEALTHCARE CENTERS & AFFILIATES

CANCER CONSORTIUM

HEALTH SERVICE(S)

UNIVERSITIES
State University
College of Nursing
SCHOOLS

OTHER – Physician Practice, Independent Investigators

NONLOCAL
Research Conduct Organizations and Participating Sites

Curriculum Vitae
PRINCIPAL INVESTIGATOR

Relationship to Subjects
Provider / Nonprovider

Relationship to Conduct Site
Employee/ Student / Independent

APPLICATION TYPE

RESEARCH
FDA and/or DHHS

NONRESEARCH
HUD

EXEMPTION

SUBJECT POPULATION

Adult / Minors
Patient / Nonpatient
Provider / Nonprovider
Student: Resident / Graduate / Undergraduate

ORGANIZATIONAL POLICY
RESEARCH
FWA IRB of Record

IRB POLICY
Confidentiality
Conflict of Interest
Standard Operating Procedures

FUNDING SOURCE

FUNDED
For profit vs
Not for profit

Private vs.
Governmental
Federal/State

UNFUNDED
(Sponsored by Conduct Organization and/or PI/Self-funded)

APPLICABLE REGULATIONS
DHHS & FWA
FDA / HIPAA
FERPA / PPRA

IRB REVIEW LEVEL

CONVENED
(FULL-BOARD, VOTING)

VS.

EXPEDITED
(DELEGATED REVIEW)

IRB REVIEW CLASSIFICATIONS

For approval:
--Voting vs. Expedited--

NEW PROTOCOL
~
REVISION / AMENDMENT / ADVERTISEMENT, etc.
~
PERIODIC REVIEW

Vs. Informational / Action Item

ADVERSE EVENT
~
CHANGE OF STATUS
~
EXEMPTION
EMERGENCY USE

Consent or WAIVER

HIPAA Authorization or WAIVER

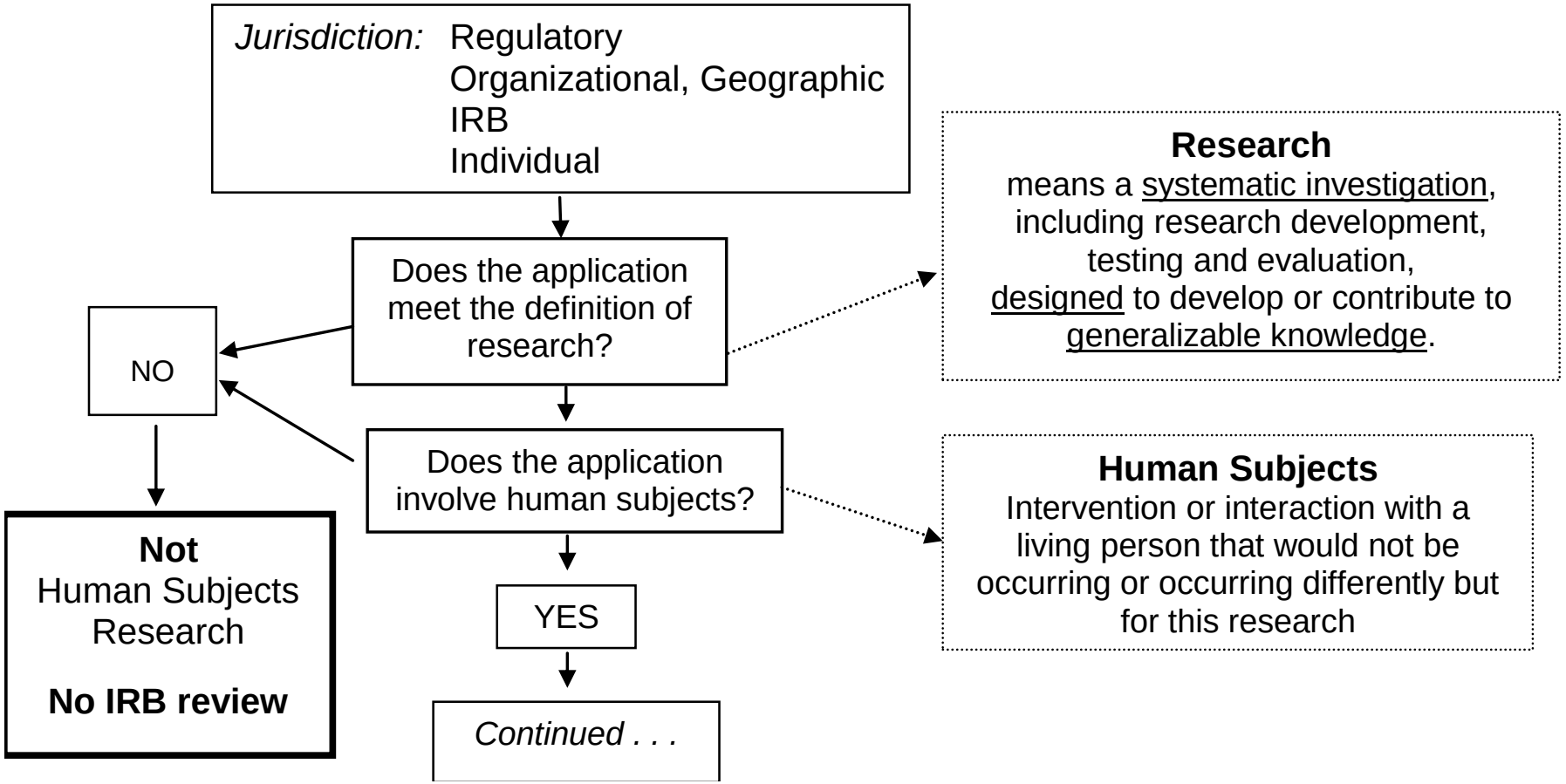
OTHER DOCUMENTATION
Permissions, Approvals, Forms, etc.

IRB Flowchart for Research Review *(continued)*

Meeting the definition of

research in human subjects

IRB of Billings – Flowchart for Research Review



IRB Flowchart for Research Review *(continued)*

Clarifying when to use “expedited” IRB review procedures :

- **Convened and full-board**
- **Expedited (“minimal risk”)**

IRB Flowchart for Research Review *(continued)*

Process and documents for

- Consent

and, if research involves patients,

- HIPAA authorization

or

- Request for IRB waiver(s)

Institutional Review Board (IRB) of Billings

Billings, Montana

Stephanie Fofonoff BS MHA
Administrator

Certified IRB Professional

Billings Clinic℠

St. Vincent Healthcare

Sisters of Charity of Leavenworth Health System

HRSA Contact

Kyle Peplinski, MA
Public Health Analyst
U.S. Department of Health and Human Services
Health Resources and Services Administration
Bureau of Health Professions
5600 Fisher Lane, Rm. 9-36
Rockville, MD 20857
301-443-7758
kpeplinski@hrsa.gov

HRSA Grantee Technical Assistance
A-TrACC

U.S. Department of Health and Human Services
HRSA
Health Resources and Services Administration